IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
AIKEN DIVISION

R. MARCUS HUFF, JR. Individually and as Personal Representative of the Estate of Elaine F. Huff, Deceased,

Plaintiffs,

v.

CENTOCOR, INC.; JOHNSON & JOHNSON; ORTHO-McNEIL PHARMACEUTICAL, INC.; MANUFACTURERS A-Z, and DISTRIBUTORS A-Z,

Defendants.

Civil Action No. 1 04 1279 24

NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §§ 1441 and 1446, and in accordance with Local Rules 83.IV.01 and 83.IV.02, the Defendants, Centocor, Inc., Johnson & Johnson, and Ortho-McNeil Pharmaceutical, Inc., hereby file this Notice of Removal to remove the captioned action from the Circuit Court for the Second Judicial Circuit, Aiken County, South Carolina, Case No. 04-CP-02-454, to the United States District Court for the District of South Carolina, Aiken Division. The removal of this civil action is proper because:

1. Centocor, Inc., Johnson & Johnson, and Ortho-McNeil Pharmaceutical, Inc., are the only named Defendants in this civil action filed in the Circuit Court for the Second Judicial Circuit, Aiken County, South Carolina, Case No. 04-CP-02-454 (the "State Court Action"). The Plaintiff included fictitious name designations for "Manufacturers A-Z" and "Distributors A-Z" as potential Defendants, but Plaintiffs have not named any additional specific Defendants other

(1)

than Centocor, Inc., Johnson & Johnson, and Ortho-McNeil Pharmaceutical, Inc.

2. Aiken County is within the District of this Court.

3. On March 25, 2004, the Plaintiffs filed the Complaint in the State Court action.

4. A copy of the Summons and Complaint was served on Centocor, Inc., Johnson & Johnson, and Ortho-McNeil Pharmaceutical, Inc., on March 26, 2004.

5. A copy of the Summons and Complaint and all other process, pleadings and orders served on Centocor, Inc., Johnson & Johnson, and Ortho-McNeil Pharmaceutical, Inc., in the State Court Action are attached hereto as Exhibit 1 pursuant to 28 U.S.C. §1446(a).

6. This removal petition is timely filed within thirty (30) days after Centocor, Inc., Johnson & Johnson, and Ortho-McNeil Pharmaceutical, Inc., were first served with the Summons and Complaint. See 28 U.S.C. §1446(b).

7. This action is subject to removal pursuant to 28 U.S.C. §1441(a), because it is within the original jurisdiction of the United States District Court under 28 U.S.C. §1332(a).

8. There is diversity of citizenship between the Plaintiffs and Defendants under 28 U.S.C. §1332(a) in that:

(a) The Plaintiffs are citizens and residents of South Carolina. See Complaint, ¶1;

(b) The Defendant Centocor, Inc., is a citizen of Pennsylvania pursuant to 28 U.S.C. §1332(c), because it is a corporation organized and existing under the laws of Pennsylvania and has its principal place of business in Pennsylvania. See Complaint, ¶2;

(c) The Defendant Johnson & Johnson is a citizen of New Jersey pursuant to 28 U.S.C. §1332(c), because it is a corporation organized and existing under the laws of New Jersey and has its principal place of business in New Jersey. See Complaint, ¶4; and

(d) The Defendant Ortho-McNeil Pharmaceutical, Inc., is a citizen of Delaware and New Jersey pursuant to 28 U.S.C. §1332(c), because it is a corporation duly organized and existing under the laws of Delaware and has its principal place of business in New Jersey. See Complaint, ¶6.

9. The amount in controversy in this civil action is not specifically pled in the Complaint. However, the plaintiffs seek damages for pain and suffering, mental anguish, wrongful death, punitive damages, and damages for alleged unfair practices. Given the Plaintiffs' allegations in the Complaint, the Defendants reasonably believe that the amount of damages sought by the Plaintiffs in this action, and therefore, the amount in controversy, exceeds Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs.

10. Pursuant to 28 U.S.C. §1446(d), a copy of this Notice of Removal will be filed with the Clerk of the Circuit Court for the Second Judicial Circuit, Aiken County, South Carolina.

11. Pursuant to 28 U.S.C. §1446(d), written notice of this Notice of Removal will also be served upon the Plaintiff.

WHEREFORE, the Defendants, Centocor, Inc., Johnson & Johnson, and Ortho-McNeil Pharmaceutical, Inc., having shown that the State Court Action is properly removable under diversity jurisdiction, respectfully request the Court to exercise its jurisdiction over the State Court Action.

Respectfully submitted, this 23 day of April, 2004.

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CERTIFICATE OF SERVICE

This is to certify that on this date I served a copy of the foregoing **Notice of Removal** on the opposing party and co-defendant to this action by depositing a copy thereof in the U.S. Mail, postage prepaid, and addressed as follows:

Fred Thompson, Esq.
Motley Rice LLC
28 Bridgeside Boulevard
Post Office Box 1792
Mount Pleasant, SC 29465

This 23 day of April, 2004.

Marsha J. Moore

Marsha J. Moore
Parker, Poe, Adams & Bernstein L.L.P.
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STATE OF SOUTH CAROLINA **COUNTY OF AIKEN**	**IN THE CIRCUIT COURT FOR THE SECOND JUDICIAL CIRCUIT** **CASE NO: 04-CP-02-454**
R. MARCUS HUFF, JR., Individually and as Personal Representative of the Estate of Elaine F. Huff, Deceased, **Plaintiffs,** **v.** **CENTOCOR, INC.; JOHNSON & JOHNSON; ORTHO-McNEIL PHARMACEUTICAL, INC.; MANUFACTURERS A-Z, and DISTRIBUTORS A-Z,** **Defendants.**	**SUMMONS** **(JURY TRIAL DEMANDED)**

TO THE DEFENDANTS ABOVE NAMED:

YOU ARE HEREBY SUMMONED and required to answer the Complaint in this action, a copy of which is herewith served upon you, and to serve a copy of your Answer to the said Complaint on the subscriber, Fred Thompson, III, Esquire, at his office at the address below, within thirty (30) days after the service hereof, exclusive of the day of such service.

YOU ARE HEREBY GIVEN NOTICE FURTHER that if you fail to appear and defend and fail to answer the Complaint as required by this Summons within thirty (30) days after the service hereof, exclusive of the day of such service, judgment by default will be entered against you for the relief demanded in the Complaint.

STATE OF SOUTH CAROLINA
COUNTY OF AIKEN
I, Liz Godard, Clerk of Court of Common Pleas and General Sessions for Aiken County, South Carolina do hereby certify that the foregoing constitutes a true and correct copy of the original documents which have been filed in my office this

MAR 25 2004

Liz Godard
C.C.C.P. & G.A., Aiken County, S.C.

Miranda Brown
Deputy Clerk

Fred Thompson by Eric Bates

Fred Thompson, Esquire (SC Bar # 5548)
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Telephone - (843) 216-9000
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Fthompson@motleyrice.com

ATTORNEY FOR PLAINTIFFS

Mt. Pleasant, South Carolina
March 25, 2004

STATE OF SOUTH CAROLINA **COUNTY OF AIKEN**	**IN THE CIRCUIT COURT FOR THE SECOND JUDICIAL CIRCUIT** **CASE NO: 04-CP-02-454**
R. MARCUS HUFF, JR., Individually and as Personal Representative of the Estate of Elaine F. Huff, Deceased, **Plaintiffs,** **v.** **CENTOCOR, INC.; JOHNSON & JOHNSON; ORTHO-McNEIL PHARMACEUTICAL, INC.; MANUFACTURERS A-Z, and DISTRIBUTORS A-Z,** **Defendants.**	**COMPLAINT** **(JURY TRIAL DEMANDED)** **Fraud** **Negligence** **Strict Liability** **Breach of Warranties** **Negligent Misrepresentation** **Violation of Consumer Protection Act** **Survival** **Wrongful Death** **Loss of Consortium**

Now comes the plaintiff R. Marcus Huff, Jr., individually and as personal representative of the estate of Elaine F. Huff, deceased, a citizen and resident of the State of South Carolina, and duly appointed in Aiken County, and brings this action against defendants on behalf of himself and as spouse, and on behalf of the estate and the legal beneficiaries of the estate, and alleges as follows (as used hereinafter, plaintiff refers to the deceased and/or her representative):

PARTIES AND JURISDICTION

1. At all times relevant to the facts herein, plaintiff is a resident and citizen of South Carolina.

2. Defendant Centocor, Inc. is a Pennsylvania corporation with its principal place of business at 200 Great Valley Parkway, Malvern, Pennsylvania, and is a wholly-owned subsidiary of defendant Johnson & Johnson.

3. Defendant Centocor, Inc. does business in South Carolina and at all times relevant hereto formulated, developed, manufactured, labeled, promoted, marketed, distributed and/or sold Remicade® (infliximab) in interstate commerce, including in South Carolina, and derived substantial revenue from these activities.

4. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

5. Defendant Johnson & Johnson does business in South Carolina and at all times relevant hereto formulated, developed, manufactured, labeled, promoted, marketed, distributed, and/or sold Remicade® (infliximab) in interstate commerce, including in South Carolina, and derived substantial revenue from these activities.

6. Defendant Ortho-McNeil Pharmaceutical, Inc. is a Delaware corporation with its principal place of business at 1000 Route 202 South, Raritan, New Jersey, and is a wholly owned subsidiary of defendant Johnson & Johnson.

7. Defendant Ortho-McNeil Pharmaceutical, Inc. does business in South Carolina and at all times relevant hereto formulated, developed, manufactured, labeled, promoted, marketed, distributed, and/or sold Remicade® (infliximab) in interstate commerce, including in South Carolina, and derived substantial revenue from these activities.

8. Defendants Manufacturers A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto formulated, developed, manufactured, labeled, promoted, marketed, distributed and/or sold Remicade® (infliximab) in interstate commerce, including in South Carolina, and derived substantial revenue from these activities.

9. Defendants Distributors A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto labeled, promoted, marketed, distributed and/or sold

Remicade® (infliximab) in interstate commerce, including in South Carolina, and derived substantial revenue from these activities.

10. That at all relevant times, defendants Centocor, Inc., Johnson & Johnson, Orthro-McNeil Pharmaceutical, Inc., Manufacturers A-Z, and Distributors A-Z, and each of them, were the agents, joint venturers, partners, parent, subsidiary, successor corporation, or representatives of each other and, in participating in the acts and omissions hereinafter alleged, were acting within the scope and course of their authority as such servants, joint venturers, partners, or representatives, and were acting with the permission and consent of each other. Together, these defendants acted in concert and/or aided and abetted each other and/or conspired to engage in common course of misconduct alleged herein for the purpose of enriching themselves at the expense of the plaintiffs.

11. That as a result of their participation in various joint ventures, parent/subsidiary relationships, and/or successor corporation, defendants Centocor, Inc., Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc., Manufacturers A-Z, and Distributors A-Z, are jointly liable to plaintiffs.

12. That as a result of their negligent supervision and actual supervision of various joint ventures, parent/subsidiary relationships, and/or successor corporations, defendants are jointly liable to plaintiffs.

13. That defendants are liable to the plaintiff, as alter egos of their joint ventures, parent/subsidiary relationships, and/or successor corporations.

14. That this Court has subject matter jurisdiction over this action.

15. That this Court has personal jurisdiction over the parties to this action.

16. That venue is proper in this Court.

THE PLAINTIFF

17. On or about August 15, 2000, decedent Elaine Huff was prescribed Remicade® for the treatment of Crohn's Disease.

18. On or about August 15, 2000 decedent received Remicade® through intravenous infusion without any knowledge of the serious, debilitating and deadly side effects that Remicade® could cause or could be a significant contributing factor, including but not limited to serious infections, sepsis, nervous system disorders, blood disorders, tuberculosis, congestive heart failure, lupus, and fatalities.

19. Decedent Elaine Huff received approximately one Remicade® infusion.

20. At the time decedent Elaine Huff was prescribed Remicade® she was not suffering from Mycobacterium Avium Complex (MAC).

21. At the time decedent Elaine Huff was prescribed Remicade® she was not suffering from tuberculosis.

22. Following the prescription and administration of Remicade®, decedent Elaine Huff suffered physical illness, injury and death, including but not limited to Mycobacterium Avium Complex (MAC) and tuberculosis.

23. As a result of her injuries, Mrs. Huff died on or about March 28, 2001.

24. As a direct and proximate result of the acts and/or omissions of the defendants, jointly and severally, plaintiff Elaine F. Huff sustained permanent, devastating injuries, and death. These injures caused extensive pain and suffering, emotional distress, a substantial reduction in Mrs. Huff's ability to enjoy life, as well as economic loss, including diminished loss of earning capacity, and expenditure of substantial sums of money for medical, hospital, and related care.

FACTUAL BACKGROUND

25. Remicade® (infliximab), a biological product, is a chimeric monoclonal antibody specifically directed against human tumor necrosis factor alpha (TNFα). Infused intravenously, it specifically targets and irreversibly binds to TNFα, a component of the body's natural defenses against serious infection. As such, it is an immune-suppressing product.

26. On August 24, 1998 the U.S. Food and Drug Administration ("the FDA") approved Remicade® for the treatment of Crohn's Disease.

27. On November 10, 1999, the FDA approved Remicade® for use in the treatment of Rheumatoid Arthritis ("RA").

28. Defendant Centocor, Inc. and defendant Ortho-McNeil Pharmaceutical, Inc., under the direction of defendant Johnson & Johnson, co-promoted Remicade® to health care providers and consumers.

29. Defendants Centocor, Inc., Johnson & Johnson and Ortho-McNeil Pharmaceutical, Inc., jointly and/or severally designed, created, manufactured, packaged, labeled, distributed, supplied, marketed, sold, promoted and/or advertised Remicade®, and/or controlled such processes.

30. At the time Remicade® was initially marketed, the product's labeling did not provide adequate warning or advice regarding the risk of MAC and other life threatening and/or life changing diseases in patients administered Remicade®.

31. At the time Remicade® was initially marketed, the product's labeling did not provide adequate warning or advice regarding the risk of tuberculosis and other life threatening and/or life changing diseases in patients administered Remicade®.

32. Prior to decedent's use of this medication, information known by the defendants showed that the use of Remicade® could result in tuberculosis, histoplasmosis, listeria sepsis, invasive fungal infections, lymphoma, pneumocystosis, seizures, multiple sclerosis, lupus,

serious infections, heart failure, and death.

33. Defendants failed to provide adequate and/or timely warnings to physicians and consumers, including decedent Elaine Huff, of the frequency and severity of adverse effects that could be caused by Remicade® including MAC and tuberculosis.

34. At the time decedent was prescribed and administered Remicade® she was not warned of the serious and debilitating health effects it could cause or to which it could be a significant contributing factor, including but not limited to MAC and tuberculosis.

35. Defendants were represented at a July 12, 2000 meeting of the Arthritis Advisory Committee that discussed Remicade® and the results of a clinical study, the Anti-TNF Trial in Rheumatoid Arthritis with Concomitant Therapy ("ATTRACT"). ATTRACT was a two-year, placebo-controlled, double-blind randomized study of repeated infliximab treatment with concomitant methotrexate therapy in patients with an inadequate response to methotrexate alone. Primary endpoints of the study were predefined for treatment of signs and symptoms at 30 weeks, prevention of structural damage at 54 weeks, and improvement in physical function at 102 weeks. ATTRACT was an international, multi-center study which included 34 sites in the U.S., Canada and Europe.

36. Eight deaths had occurred through week 54 of the ATTRACT trials. Three deaths occurred in patients given a placebo and five deaths in those given infliximab. As to the deaths in infliximab recipients, one died of pulmonary embolism, two died of cardiopulmonary events, one died of tuberculosis and one died of coccidioidomycosis ("Valley Fever").

37. At the Arthritis Advisory Committee meeting, a representative of defendant Centocor, Inc. stated that long-term safety follow-up and post-marketing experience demonstrated that Remicade® is "safe and well tolerated," notwithstanding that at least 10 percent of Remicade®-treated patients had suffered upper respiratory infection, headaches, sinusitis, coughing, rash, abdominal pain, fatigue and pharyngitis; that the most frequent serious

infections included pneumonia, cellulitis, urinary tract infections, bacterial infections not otherwise specified and sepsis; that one patient had died of tuberculosis and another had died of coccidioidomycosis; that three patients developed symptoms suggestive of drug-induced lupus; and that one patient developed a non-Hodgkin's lymphoma prior to 20 weeks, two patients developed non-Hodgkin's lymphoma during three year and one patient developed Hodgkin's lymphoma.

38. Defendant Centocor, Inc.'s representative further asserted that there was "substantial post-marketing safety experience outside of the completed and ongoing trials" of Remicade®; that the reported number of patients with serious infections--including sepsis, tuberculosis and opportunistic infections--as well as malignancies and deaths, was low; and that the safety profile was "consistent with the current package insert."

39. On or about August 15, 2001, a "Black Box Warning" was added to the Remicade® label warning that tuberculosis, invasive fungal infections and other opportunistic infections have been observed in patients receiving Remicade® and that some of these infections have been fatal. At the same time, a warning was added to the package insert noting that cases of histoplasmosis, listeriosis, pneumocystosis and tuberculosis have been observed in patients receiving Remicade®, and advising that "[f]or patients who have resided in regions where histoplasmosis is endemic, the benefits and risks of Remicade treatment should be carefully considered before initiation of Remicade therapy."

40. Although changes may have been made to product labeling and packaging inserts in August 2001, in was not until October 5, 2001, that defendant Centocor, Inc. informed some health care professionals of these changes when they sent a letter stating that tuberculosis and other serious opportunistic infections, including histoplasmosis, listeriosis, and pneumocystosis, had been reported in both the clinical research and post-marketing surveillance settings. Some of these infections had been fatal. The letter refers the health care professional to the August

15, 2001 revisions to the labeling for Remicade® including the Black Box Warning. According to the manufacturer, at least 84 cases of tuberculosis had been reported in patients using Remicade®.

41. On October 11, 2001, an article entitled, "Tuberculosis Associated with Infliximab, a Tumor Necrosis Factor a-Neutralizing Agent," appeared in the New England Journal of Medicine. The authors of this study found that there were 70 reported cases of tuberculosis after treatment with infliximab for a median of 12 weeks. In 48 patients, tuberculosis developed after three or fewer infusions. Sixty-four of these patients were from countries with a low incidence of tuberculosis. The reported frequency of tuberculosis in association with infliximab therapy was much higher than the reported frequency of other opportunistic infections associated with this product, and the rate of reported cases of tuberculosis in infliximab-treated patients was 300 percent higher than in the general rheumatoid arthritis population. The article concluded that initiation of treatment with infliximab can cause active tuberculosis.

42. On October 18, 2001, defendant Centocor, Inc. sent a second letter to health care professionals advising that they should not initiate Remicade® therapy in patients with congestive heart failure, to discontinue Remicade® in patients whose congestive heart failure is worsening and to consider discontinuing Remicade® in patients with stable congestive heart failure. In its letter, Centocor reported that in its ongoing trial in 150 patients with moderate to severe (NYHA class III-IV) congestive heart failure (CHF), higher incidences of mortality and hospitalization for worsening heart failure were seen in patients treated with Remicade®; seven of 101 patients treated with Remicade® had died compared to no deaths among the 49 patients given placebo.

43. In January 2002, based upon adverse drug reactions reports known to defendants, the FDA issued a warning about serious nervous system problems involving demyelinization,

MS and other conditions, associated with the use of Remicade®.

44. At all times relevant hereto, defendants continued to aggressively market Remicade® to doctors, potential consumers, and existing Remicade® users as safe and highly effective.

45. Despite defendants' knowledge that Remicade' was a cause or a substantial contributing factor to sepsis, blood disorders, pneumonia, drug-induced lupus, serious infection, congestive heart failure and nervous system disorders, physicians and their patients, including decedent, were not told or not timely told that symptoms of sepsis or other illness may be indicative of an adverse reaction to Remicade®, nor that they were at a higher risk of suffering from sepsis, congestive heart failure, or blood disorders or other illness as a result of taking Remicade®.

46. Defendants falsely and deceptively misrepresented and/or omitted material facts in marketing Remicade® to physicians and the public, including decedent, including but not limited to the adverse health effects caused by Remicade® and the frequency, severity and rapid development of these adverse effects.

47. To date, defendants have failed to adequately advise physicians, potential Remicade® users, and Remicade® users of any strategies necessary to prevent, quickly identify and properly treat infections that occur at a much higher percentage in persons taking Remicade® and which can be seriously debilitating and/or fatal.

48. To date, defendants have failed to adequately advise physicians, potential Remicade® users, and Remicade® users that laboratory signs of infection may be blunted by TNF blockage and by concomitant immunosuppressive medication and to advise them that more effective diagnostic procedures and the need to act quickly in treating any infection in an individual prescribed Remicade®.

49. Defendants have advertised and promoted Remicade®, as a safe and effective

product for the reduction in signs and symptoms of Crohn's Disease and symptoms of moderately to severely active rheumatoid arthritis.

50. Defendants have created, financed, assisted, supported and/or participated in medical advertising to create consumer demand for Remicade®.

51. Defendants have created, financed, assisted, supported, participated, supplied and knew of the use of their pamphlets, brochures, advertisements and other promotional materials for Remicade® in the offices of doctors, hospitals and other health care providers and on the Internet.

52. Defendants' aggressive marketing strategy included hiring a health care advertising agency to handle their professional, consumer and international advertising accounts for Remicade®.

53. Collectively, defendants sold Remicade® by misleading and misinforming potential users and by failing to protect users from serious dangers that defendants knew or should have known would result from use of this product.

54. Defendants purposefully and consciously ignored and/or understated the health risks associated with Remicade®.

55. Defendants' marketing misconduct includes the use of testimonials from purportedly satisfied users and the abuse of statistics to suggest acceptability in the medical and lay community, while known serious reactions and dangerous health risks were not publicized and those risks that were identified were downplayed.

56. Defendants' marketing misconduct further includes marketing the profitability of prescribing Remicade® to physicians. Sometime before a April 2002, defendant Centocor, Inc.'s website told doctors that one "benefit" of prescribing Remicade® was the "financial impact" on the physician's practice. The website included a worksheet where physicians could calculate their "estimated revenue per patient" from prescribing the product. This "revenue"

was primarily the difference between what Medicare pays doctors for Remicade® and the lower amount that Centocor would actually charge doctors for the product. This increased profitability for the practitioner was designed to induce physicians to prescribe Remicade rather other medications.

FOR A FIRST CAUSE OF ACTION – FRAUD
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

57. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

58. That at all times during which defendants promoted, marketed, distributed, developed, manufactured, labeled and sold Remicade, defendants knowingly, intentionally, willfully, and purposefully deceived decedent by (1) making false and fraudulent, material misrepresentations to her, her physicians and the general public, regarding Remicade's safety; and (2) concealing from decedent, her physicians, and the general public the true facts known by defendants concerning the safety of Remicade.

59. That defendants knew their representations were false and inaccurate.

60. That the true and accurate facts were knowingly and intentionally concealed by defendants that Remicade was associated with and known to cause severe adverse effects including those decedent suffered and died from.

61. That defendants knew this information, and intentionally withheld this information from decedent and other members of the general public who purchased and administered Remicade.

62. That defendants made the above mentioned misrepresentations and intentional concealment to decedent and other consumers, knowing the misrepresentations were false and inaccurate, with the intent to deceive decedent and the public who were ignorant of the true facts, and with the intent to induce the public and decedent to use Remicade.

63. That decedent had no knowledge of the falsity of defendants and intentional concealment at the time she purchased and consumed Remicade, and in reliance upon defendants' misrepresentations, decedent believed Remicade to be safe for use.

64. That decedent reasonably relied upon defendants' misrepresentations and was induced to receive and did in fact receive a Remicade infusion for the treatment of Crohn's disease.

65. That decedent would not have used Remicade if she had known and had been informed of the true facts concerning the connection of Remicade and the aforementioned severe and life threatening medical condition from which she suffered and died.

66. That decedent justifiably and reasonably relied upon defendants' misrepresentations because defendants were in a special and fiduciary relationship to decedent in that defendants held themselves out to have experience in the field of biologicals and knew that consumers like decedent would use Remicade.

67. That decedent's reliance upon defendants' misrepresentations was reasonable, as she did not, at all times relevant to this action, have the knowledge and/or expertise necessary to independently evaluate whether or not Remicade was safe.

68. That the foregoing misrepresentations and intentional concealment by defendants were made with the intent to willfully induce decedent and other members of the public to use Remicade.

69. That as a direct and proximate result of defendants' fraudulent and deceitful conduct, plaintiff suffered injury and economic loss, and further damages as set forth herein.

70. 70. That at all material times, defendants knew of the defective nature of their product as set forth herein, and continued to design, manufacture, market, label, and sell Remicade so as to maximize sales and profits at the expense of public health and safety, and as such defendants' conduct, jointly and/or severally, exhibits a wanton and reckless disregard for human life; and further, defendants, jointly and/or severally, exhibited such an entire want of care as to establish that their actions were a result of fraud, actual malice and a conscious and deliberate disregard of foreseeable harm to plaintiff herein, thereby entitling plaintiff to punitive damages.

FOR A SECOND CAUSE OF ACTION – NEGLIGENCE/GROSS NEGLIGENCE
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

71. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

72. That at all material times, defendants, jointly and/or severally, had a duty to exercise reasonable care in all aspects of the designing, developing, testing, labeling, marketing, distributing, selling and warning regarding the use of Remicade, to ensure the safety of Remicade and to ensure that the consuming public, including decedent her physicians, obtained accurate information and instructions for the safe use of Remicade.

73. That defendants, jointly and/or severally, failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control and/or distribution of Remicade into interstate commerce and that defendants knew or should have known that this product

created a high risk of unreasonable, dangerous side effects which could only be alleviated by surgery or other invasive procedures, or which could not be treated at all but which cause severe permanent injury and which can be fatal.

74. That defendants, jointly and/or severally, were negligent in the promotion, design, manufacture, testing, labeling advertising, warning, marketing and sale of Remicade in at least the following particulars:

a. Failing to use due care in the design and manufacturing of Remicade so as to avoid risks to decedent when such product was being administered for the treatment of Crohn's disease;

b. Failing to accompany their product with proper warnings regarding all possible adverse side effects associated with the use of Remicade and the comparative severity and risk of such adverse effects;

c. Failing to conduct adequate clinical testing and post-marketing surveillance to determine the safety of Remicade and failing to adequately and timely warn of the safety risks discovered through such testing and surveillance when it was done;

d. Failing to provide adequate training to medical care providers as to the appropriate use of Remicade;

e. Failing to provided adequate training to medical care providers as to how to identify individuals who have risk factors which should prohibit them from being prescribed Remicade;

f. Failing to warn decedent prior to actively encouraging the sale of Remicade either directly or indirectly, orally or in writing, about (1) the need for comprehensive, regular medical monitoring to ensure early discovery of potentially severe side effects; (2) the possibility of suffering from various severe side effects including, but not limited to, serious infections, tuberculosis, sepsis, blood disorders and death as a result of the use of Remicade; and (3) that such side effects may become protracted, debilitating, difficult and painful, necessitating lengthy surgery or several visits to the doctor, clinic or hospital, or in even fatal; and

g. In such other and further particulars as will be proven at trial.

75. That defendants, jointly and/or severally, continued to market Remicade to consumers, including decedent, despite the fact that defendants knew or should have known that Remicade caused unreasonable, dangerous side effects, which many users would be unable to remedy by any means, and when there were safer alternative treatments for Crohn's disease available.

76. That defendants knew or should have known that consumers such as decedent would suffer foreseeable injury as a result of defendants' failure, jointly and/or severally, to exercise ordinary care as described above.

77. That as a direct and proximate result of defendants' negligence, jointly and/or severally, plaintiff suffered injury and economic loss, and plaintiff has suffered damage as set forth herein.

78. That at all material times, defendants knew of the defective nature of their product as set forth herein, and continued to design, manufacture, market, label, and sell Remicade so as to maximize sales and profits at the expense of public health and safety, and as such defendants' conduct, jointly and/or severally, exhibits a wanton and reckless disregard for human life; and further, defendants, jointly and/or severally, exhibited such an entire want of care as to establish that their actions were a result of fraud, actual malice and a conscious and deliberate disregard of foreseeable harm to plaintiff herein, thereby entitling plaintiff to punitive damages.

FOR A THIRD CAUSE OF ACTION - STRICT PRODUCT LIABILITY
(FAILURE TO WARN)
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

79. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

80. That defendants knew or should have known of the serious adverse effects of Remicade when used for its intended purpose.

81. That defendants had no reason to believe that decedent would realize the serious potential dangers of using Remicade.

82. That the Remicade manufactured and/or supplied by defendants was at all materials times, unaccompanied by proper warnings concerning all possible adverse side effects including, but not limited to, the comparative severity, scope and duration of adverse effects.

83. That defendants, jointly and/or severally, also failed to effectively warn users and physicians that numerous other treatments for Crohn's disease should be first line or exclusive methods of treatment for high-risk individuals, such as those with chronic infection and/or diabetes.

84. That after defendants knew or should have known of the risk of injury from Remicade, they failed to provide adequate warnings to users or consumers of the product, and in fact continued to aggressively promote the product, and as a direct result thereof, the product manufactured and/or supplied by defendants was defective due to inadequate post-marketing warning and/or instructions.

85. That a proximate cause and legal result of the defective condition of Remicade as manufactured and/or supplied by defendants, and as a direct and legal result of the negligence, carelessness, other wrongdoing and actions of defendants, jointly and/or severally, plaintiff sustained the damages and injuries set forth above.

86. That had decedent been adequately warned by any of the defendants of the dangers of Remicade she would not have taken Remicade and would not have been damaged thereby.

87. That at all materials times, defendants, jointly and/or severally, knew of the defective nature of their product, and continued to design, manufacture, market, label, and sell Remicade so as to maximize sales and profits at the expense of public health and safety, and as such, defendants' conduct exhibits such an entire want of care as to establish that their actions were a result of fraud, actual malice, and the conscious and deliberate disregard of foreseeable harm to plaintiff.

FOR A FOURTH CAUSE OF ACTION - STRICT PRODUCT LIABILITY
(PURSUANT TO RESTATEMENT SECOND OF TORTS § 402 (1965))
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

88. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

89. That at all material times, the Remicade manufactured and/or supplied by defendants, jointly and/or severally, was placed into the stream of commerce by defendants in a defective and unreasonably dangerous condition in that the known and foreseeable risks associated with the use of this product exceeded the benefits associated with its design or

formulation.

90. That alternatively, the Remicade manufactured and/or supplied by defendants, jointly and/or severally, was defective in design or formulation, such that when it was placed in the stream of commerce, it was unreasonably dangerous in that it was more dangerous than an ordinary consumer would expect and more dangerous than other treatments for Crohn's disease which were available to Decedent.

91. That the Remicade manufactured by defendants, jointly and/or severally, was defective due to inadequate warnings or instructions since the manufacturers knew or should have known that the product created a risk of harm to consumers such as decedent when used in the way it was intended to be used and in a manner which was reasonably foreseeable by defendants.

92. That Remicade manufactured and supplied by defendants was defective due to inadequate warnings, inadequate testing, inadequate post-marketing warnings, inadequate post-marketing instructions because after defendants knew or should have known of the risk of injury from Remicade and the types of individuals that were more at risk of developing these injuries, they failed to provide adequate warnings and instructions to physicians and consumers of the product and continued to promote the product as safe and effective.

93. That the Remicade was at the time it left defendants' control, a defective product, unreasonably dangerous for use, resulting in injury to decedent as herein alleged.

94. That the defective and unreasonably dangerous condition of Remicade was the proximate cause of the damages and injuries sustained by the plaintiff.

95. That at all material times, defendants, jointly and/or severally, actually knew of the defective nature of their products as set forth herein and blatantly continued to design,

manufacture, market, label, and sell their products so as to maximize sales and profits at the expense of public health and safety, and they exhibited such an entire want of care as to establish that their actions were a result of fraud, actual malice and the conscious and deliberate disregard of foreseeable harm to plaintiff.

FOR A FIFTH CAUSE OF ACTION - BREACH OF EXPRESS WARRANTIES
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

96. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

97. That defendants, jointly and/or severally, expressly warranted that Remicade was safe for use.

98. That Remicade does not conform to these express representations because Remicade is not safe when used as intended and has serious life threatening side effects.

99. That as a direct and proximate result of the breach of express warranties by defendants, jointly and/or severally, plaintiff suffered injury and economic loss, and plaintiff has suffered damage as set forth herein.

100. That at all material times, defendants, jointly and/or severally, actually knew of the defective nature of their products as set forth herein and blatantly continued to design, manufacture, market, label, and sell their products so as to maximize sales and profits at the expense of public health and safety, and they exhibited such an entire want of care as to establish that their actions were a result of fraud, actual malice and the conscious and deliberate disregard of foreseeable harm to plaintiff.

FOR A SIXTH CAUSE OF ACTION - BREACH OF IMPLIED WARRANTIES
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

101. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

102. That defendants, jointly and/or severally, impliedly warranted to prospective purchasers and users, including decedent, that the Remicade was safe, merchantable, and fit for the ordinary purposes for which such goods are used.

103. That decedent reasonably relied upon the skill and judgment of defendants as to whether Remicade was of merchantable quality and safe and fit for its intended use.

104. That contrary to such implied warranties, Remicade, was not of merchantable quality or safe or fit for its intended use, because the product was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used as previously described above.

105. That as a direct and proximate result of the breach of implied warranties by defendants, jointly and/or severally, plaintiff suffered injury and economic loss, and plaintiff has suffered damages as set forth herein.

106. That at all material times, defendants, jointly and/or severally, actually knew of the defective nature of their products as set forth herein and blatantly continued to design, manufacture, market, label, and sell their products so as to maximize sales and profits at the expense of public health and safety, and they exhibited such an entire want of care as to establish that their actions were a result of fraud, actual malice and the conscious and deliberate disregard of foreseeable harm to plaintiff.

FOR A SEVENTH CAUSE OF ACTION - NEGLIGENT MISREPRESENTATION
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

107. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

108. That defendants owed a duty of care to decedent to ensure that truthful information was communicated to decedent, and defendants breached that duty by failing to exercise due care in making representations.

109. That defendants falsely represented to decedent and her physicians that Remicade was safe for its intended use when used as instructed and labeled. These representations were false, as Remicade was dangerous to the health of decedent when used as intended.

110. That defendants knew of the falsity of their representations.

111. That defendants failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Remicade, and otherwise failed to exercise reasonable care in communicating the information to decedent and her physicians.

112. That defendants intended for decedent and her physicians to rely on their representations in order to receive compensation for the product provided to decedent and, as such, defendants had a pecuniary interest in making such representations.

113. That decedent was unaware of the falsities of these representations.

114. That in reasonable reliance upon defendants' misrepresentations, decedent and her physician was induced to, and did, use Remicade.

115. That as a direct and proximate result of negligent misrepresentations by defendants, jointly and/or severally, plaintiff suffered injury and economic loss, and plaintiff has

suffered damage as set forth herein.

116. That at all material times, defendants, jointly and/or severally, actually knew of the defective nature of their products as set forth herein and blatantly continued to design, manufacture, market, label and sell Remicade so as to maximize sales and profits at the expense of public health and safety, and they exhibited such an entire want of care as to establish that their actions were a result of fraud, actual malice and the conscious and deliberate disregard of foreseeable harm to plaintiff, thereby entitling plaintiff to punitive damages.

FOR AN EIGHTH CAUSE OF ACTION - VIOLATION OF THE SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

117. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

118. That by reason of their conduct as alleged herein, defendants willfully and/or knowingly violated the provisions of S.C. Code § 39-5-10 *et seq.* as it refers to consumer protection by inducing decedent and her physician to use Remicade through the use of false and/or misleading advertising, representations and statements.

119. That by engaging in the conduct described above, defendants have violated this state's Unfair Trade Practices Act by, among other things:

a. Engaging in unfair or deceptive trade practices as defined in this statute by making false and misleading oral and written statements that had, and have, the capacity, tendency or effect of deceiving or misleading consumers;

b. Engaging in unfair or deceptive trade practices as defined in this statute by failing to state material facts, the omission of which deceived or tended to deceive, including but not limited to, facts relating to the health consequences of the use of Remicade; and

c. Engaging in unfair or deceptive trade practices as defined in this statute through deception, fraud, misrepresentation and knowing concealment, suppression and omission of material facts with the intent that consumers rely upon the same in connection with the use and continued use of Remicade.

120. That as a direct and proximate result of defendants' conduct in violation of the State's Unfair Trade Practices Act, jointly and/or severally, plaintiff suffered injury and economic loss, and plaintiff has suffered damage as set forth herein.

121. That at all material times, defendants, jointly and/or severally, actually knew of the defective nature of their products as set forth herein and blatantly continued to make false and/or misleading advertising, representations and statements regarding Remicade so as to maximize sales and profits at the expense of public health and safety, and they exhibited such an entire want of care as to establish that their actions were a result of fraud, actual malice and the conscious and deliberate disregard of foreseeable harm to plaintiff, thereby entitling plaintiff to both punitive and treble damages.

FOR A NINTH CAUSE OF ACTION – SURVIVAL
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

122. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

123. That as a result of the development of serious infections, including, but not limited to, Mycobacterium Avium Complex and tuberculosis, decedent suffered and sustained serious and debilitating injuries to her person requiring prolonged and extensive medical treatment and ultimately death.

124. That as a result of the aforesaid illnesses, decedent suffered conscious pain and suffering, medical and hospital expenses, personal injuries, and trauma, suffered by decedent prior to his death, and funeral expenses and other compensatory damage, and is entitled to punitive damages in an amount to be determined by the trier of fact. Plaintiff alleges entitlement to all damages allowed under the Survival Act, § 15-5-90, S.C. CODE ANN. (Law Co-op. 1976).

FOR A TENTH CAUSE OF ACTION – WRONGFUL DEATH
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

125. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

126. That as a result of the aforesaid death of Decedent, Mrs. Huff's beneficiaries have and will suffer pecuniary loss, mental shock and suffering, wounded feelings, grief and sorrow, loss of companionship, deprivation of use and comfort of decedent's society, all both past and future; and funeral expenses, all to the beneficiaries, actual damages, and further are entitled to punitive damages in an amount to be determined by the trier of fact. Plaintiff alleges entitlement to all damages allowed under the Wrongful Death Act, § 15-51-10, S.C. CODE ANN. (Law Co-op. 1976).

FOR AN ELEVENTH CAUSE OF ACTION - LOSS OF CONSORTIUM
CENTOCOR INC.
JOHNSON & JOHNSON
ORTHO-McNEIL PHARMACEUTICALS
MANUFACTURERS A-Z
DISTRIBUTORS A-Z

127. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

128. That decedent and Mr. R. Marcus Huff, Jr., were husband and wife at the time of the occurrences referred to in this Complaint and continue to be husband and wife.

129. That the conduct of defendants, set forth above, proximately caused injury to the marital relationship of Mr. Huff, including loss of society, affection, assistance, companionship and loss of sexual relation.

130. That plaintiff is entitled to actual damages against the defendants, jointly and severally, by reason of said loss of consortium and society, proximately caused by the fault of defendants, and punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

a. For general and compensatory damages including, but not limited to, pain and suffering, mental anguish, and emotional distress;

b. Medical and incidental expenses according to proof;

c. ~~Loss of past earnings and earning capacity;~~

d. Prejudgment and post-judgment interest as provided by law;

e. Full refund of all purchase costs of the Plaintiff for Remicade;

f. Consequential damages;

g. Punitive and exemplary damages;

h. Treble damages;